

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

DANA-FARBER CANCER INSTITUTE, INC.,)
)
Plaintiff,)
)
v.) Civil Action No. 1:19-cv-11380-PBS
)
BRISTOL-MYERS SQUIBB, CO.,) HIGHLY CONFIDENTIAL
E.R. SQUIBB & SONS, L.L.C., AND ONO) FILED UNDER SEAL
PHARMACEUTICAL CO., LTD.,)
)
Defendants.) Leave to file granted January 4, 2021

AMENDED AND SUPPLEMENTAL COMPLAINT

Dana-Farber Cancer Institute, Inc. (“Dana-Farber”), for its complaint against Bristol-Myers Squibb Co. (“Bristol-Myers”), E.R. Squibb & Sons, L.L.C. (“Squibb”) (Bristol-Myers and Squibb together, “BMS”), and Ono Pharmaceutical Co., Ltd. (“Ono”) (collectively, “Defendants”), alleges as follows:

INTRODUCTION

1. This is a civil action by Dana-Farber seeking damages and equitable relief to remedy Defendants' employment of unfair methods of competition, unfair trade practices, tortious interference with business relationships, and unjust enrichment. This action also seeks to remedy Defendants' refusal to correct inventorship of two additional patents issued to Tasuku Honjo and Ono in 2016, U.S. Patent No. 9,393,301 and U.S. Patent No. 9,439,962, and to obtain a judicial declaration that unless and until inventorship of the two patents is corrected, the two patents are invalid and unenforceable.

2. Defendants have unlawfully exploited the commercial benefits of multiple patents arising from a research collaboration with Dana-Farber by wrongfully (i) denying Dana-Farber's

co-ownership of the patents; (ii) depriving Dana-Farber of the licensing opportunities to which it was entitled as a co-owner; and (iii) willfully and knowingly employing unfair methods of competition and unfair trade practices to interfere with Dana-Farber's efforts to license the patents to third parties, all in order unfairly to appropriate for themselves billions of dollars in royalties and injure Dana-Farber.

3. After this Court ordered, in May 2019, that Dana-Farber scientist Gordon Freeman was wrongly omitted as an inventor of six patents issued to Honjo and Ono (the "Honjo-Freeman Patents"), Defendants have attempted to circumvent and frustrate the impact of the Court's order through additional unlawful actions intended to deprive Dana-Farber of the legitimate economic opportunities and benefits Dana-Farber should rightfully have obtained as a consequence of the Court's order.

4. In furtherance of their unlawful scheme, Defendants imposed restrictive and anticompetitive covenants on licensees of the Honjo-Freeman Patents that conditioned Defendants' licensing of intellectual property on the licensees' agreement not to deal with Dana-Farber. The effect was to coerce licensees to pay, or agree to pay, hundreds of millions of dollars more in royalties to Defendants than the licensees would have needed to pay Dana-Farber to obtain freedom to operate under the Honjo-Freeman Patents. By these and other wrongful actions, Defendants caused substantial economic harm to Dana-Farber, constrained Dana-Farber's ability to devote scarce resources to cancer research and patient care, and increased the costs imposed on manufacturers of PD-1/PD-L1 therapies approved for the treatment of cancer.

5. The Honjo-Freeman Patents are directed to methods of cancer immunotherapy involving the administration of PD-1 or PD-L1 antibodies. The United States District Court for the District of Massachusetts ("the Court") held, in its May 17, 2019 decision in *Dana-Farber*

Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al. (the “inventorship case”) that Dana-Farber scientist Gordon Freeman should have been named as a joint inventor of those patents, and thus that Dana-Farber should have been able to exercise the rights of a co-owner. *See* Dkt. No. 389, Findings of Fact, Conclusions of Law, and Order, *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. May 17, 2019) (the “Decision”); Dkt. No. 394, Judgment, *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. June 12, 2019). On July 14, 2020, the Federal Circuit affirmed the Court’s judgment. *See Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co.*, 964 F.3d 1365 (Fed. Cir. 2020).

6. Defendants have long known of Freeman’s scientific contributions to the Honjo-Freeman Patents and Dana-Farber’s rightful co-ownership of them. Yet by denying Dana-Farber’s co-ownership of the Honjo-Freeman Patents, by obstructing, hindering, and delaying correction of their inventorship, by holding themselves out to third parties as exclusive owners of the patents, and by conditioning their grant of third-party patent licenses on terms that prevent Dana-Farber from fairly competing for licensees, Defendants unfairly appropriated for themselves the ability both to sue their competitors for infringement of the Honjo-Freeman Patents without Dana-Farber’s consent and to negotiate lucrative licensing deals that have generated some \$3 billion in licensing revenue for Defendants.

7. Defendants have continued to their pattern of interfering with Dana-Farber’s prospective business relationships even after the Court ordered correction of inventorship. On information and belief, Defendants have improperly induced prospective licensees not to enter business relationships with Dana-Farber, and they have used their ownership of additional patents in the PD-1/PD-L1 field, to pressure licensees to license the Honjo-Freeman Patents from

Defendants rather than Dana-Farber, requiring the licensee to pay more to Defendants in royalties than the licensees would have been required to pay to Dana-Farber for a license to those same patents.

8. Among the additional patents Defendants have used to pressure prospective licensees not to deal with Dana-Farber are two patents that issued in the same family as the Honjo-Freeman Patents. These patents claim priority to the same Japanese patent applications as the Honjo-Freeman Patents and name as inventors only the same four Japanese scientists who originally were named as inventors on the Honjo-Freeman Patents. These two patents, U.S. Patent No. 9,393,301 (the '301 patent) and U.S. Patent No. 9,439,962, (the '962 patent), like claim methods of treating tumors by administering anti-PD-L1 antibodies. The Court's findings in 2019 that Gordon Freeman and Clive Wood made significant contributions to conception of the Honjo-Freeman Patents, affirmed in all respects by the United States Court of Appeals for the Federal Circuit, apply with the same force to these two additional patents and have preclusive effect. Dana-Farber requested that Ono voluntarily correct the inventorship of the '301 and '962 patents, but Ono has unjustifiably and maliciously refused to do so, even though failure to correct inventorship is contrary to Defendants' own interests because unless and until the patents are corrected, they are invalid and unenforceable.

9. Defendants' actions unfairly deprived Dana-Farber of the opportunity to grant royalty-bearing licenses to potential licensees known to Defendants, and those actions robbed Dana-Farber of the licensing revenue Defendants unfairly seized for themselves. As set forth below, Dana-Farber seeks money damages and equitable remedies for Defendants' unfair methods of competition, unfair trade practices, tortious interference, and unjust enrichment in violation of the law of contracts, torts, and Massachusetts General Laws Chapter 93A. Dana-

Farber further seeks correction of inventorship of the '301 and '962 patents or, in the alternative, if the patents are not corrected, a declaration that the '301 and '962 patents are invalid and unenforceable, so that Defendants can no longer use them as leverage to coerce potential licensees to license the Honjo-Freeman Patents from Defendants rather than from Dana-Farber.

THE PARTIES

10. Dana-Farber is a Massachusetts non-profit corporation with a place of business at 450 Brookline Avenue, Boston, Massachusetts 02215. Since its founding in 1947, Dana-Farber has been committed to providing adults and children suffering from cancer with the best treatments available today while also developing future therapies through cutting-edge research. As an affiliate of Harvard Medical School and a Comprehensive Cancer Center designated by the National Cancer Institute, Dana-Farber also provides training for new generations of physicians and scientists; designs programs that promote public health, particularly among high-risk and underserved populations; and disseminates innovative patient therapies and scientific discoveries across the United States and throughout the world, all with the goal of defeating cancer.

11. As a leader in basic, translational, clinical, and population science research, Dana-Farber prides itself on its emphasis on both research and patient care. Dana-Farber helps to advance this mission through, among other things, licensing its intellectual property. Licensing partnerships help to support Dana-Farber's vital cancer research and patient care, and translate Dana-Farber's research discoveries into new products made widely available for diagnosing and treating cancer. Dana-Farber's licensing program also generates revenue for Dana-Farber that can be re-invested in future cancer research and patient care.

12. Dana-Farber is the assignee of Freeman's rights and interest as an inventor in the inventions claimed in the Honjo-Freeman Patents: U.S. Patent No. 7,595,048 (the "'048

patent”); U.S. Patent No. 8,168,179 (the “179 patent”); U.S. Patent No. 8,728,474 (the “474 patent”); U.S. Patent No. 9,067,999 (the “999 patent”); U.S. Patent No. 9,073,994 (the “994 patent”); and U.S. Patent No. 9,402,899 (the “899 patent”). Dana-Farber is also the assignee of Freeman’s rights and interest as an inventor in the inventions claimed in the ’301 patent and the ’962 patent.

13. On information and belief, Bristol-Myers is a corporation organized under the laws of the State of Delaware, with a principal place of business at 345 Park Avenue, New York, New York 10154.

14. On information and belief, Squibb is a limited liability company organized under the laws of the State of Delaware, with a principal place of business at Route 206 & Province Line Road, Princeton, New Jersey 08543.

15. On information and belief, Ono is a corporation organized under the laws of Japan, with a place of business at 8-2 Kyutaromachi 1-chome, Chuo-ku, Osaka 541-8654, Japan. Named inventor Shiro Shibayama is, and at all relevant times was, an employee of Ono. BMS is the exclusive licensee of Ono’s rights in the Honjo-Freeman Patents and in the ’301 and ’962 patents.

JURISDICTION

16. This court has jurisdiction under 28 U.S.C. §§ 1331, 1332, and 1367. The amount in controversy exceeds \$75,000, exclusive of interest and costs.

17. Venue is proper in this judicial district under 28 U.S.C 1391(b).

18. This Court has personal jurisdiction over Bristol, Squibb, and Ono to adjudicate this action.

FACTUAL BACKGROUND

The Technology

19. The Honjo-Freeman Patents stem from the pioneering work of Freeman and Clive Wood, Ph.D., former head of drug development at Genetics Institute, in a research collaboration with Tasuku Honjo, Ph.D. of Kyoto University that led to the development of cancer immunotherapy treatment methods claimed in the Patents.

20. The Honjo-Freeman Patents disclose groundbreaking methods of “using the body’s immune system to attack tumor cells, a type of treatment known as cancer immunotherapy.” Decision at 11.

21. The Honjo-Freeman Patents describe methods that target an “inhibitory receptor on T cells known as PD-1.” *Id.* at 9. As the Court explained, immune cells communicate through receptor-ligand interactions. “The receptor receives a signal from outside the cell and then transmits the signal to the internal components of the cell to trigger a response. Ligands are proteins that bind to receptors to initiate signaling.” *Id.* at 7.

22. As the Court further explained, “[w]hen PD-1 binds to one of its ligands, PD-L1 or PD-L2, the T cell receives an inhibitory signal that prevents it from attacking the cell expressing PD-L1 or PD-L2.” *Id.* at 9. In healthy cells, expression of those ligands “protects the cells from immune attack. Some tumor cells also express PD-L1 or PD-L2, allowing them to masquerade as healthy cells by activating PD-1 to send an inhibitory signal to T cells.” *Id.*

Inventorship of the Honjo-Freeman Patents

23. In its May 17, 2019 Decision, the Court found that Freeman and Wood collaborated with Honjo, a professor at Kyoto University, “from at least October 1999 until at least September 2000 through numerous meetings, joint authorship of scientific journal articles,

written collaboration agreements, and sharing of experimental results and ideas.” *Id.* at 5. The Court concluded that “all three made significant contributions to the inventions” claimed in the Honjo-Freeman Patents. *Id.* The Federal Circuit agreed, holding that “Drs. Freeman and Wood’s work linking PD-1 to its ligand and expression in tumors was a significant contribution to each of these patents’ conception.” *Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co.*, 964 F.3d 1365, 1374 (Fed. Cir. 2020). Despite this, in prosecuting the Honjo-Freeman Patents, Ono listed as inventors only Honjo; two of his current or former colleagues at Kyoto University, Nagahiro Minato and Yoshiko Iwai; and Ono scientist Shiro Shibayama.

24. The Honjo-Freeman Patents all claim priority to two Japanese patent applications, Japanese Patent Applications 2002-194491 and 2003-029846 (the “Japanese Patent Applications”). On July 3, 2002, Ono filed Japanese Patent Application 2002-194491. Ono then filed Japanese Patent Application 2003-029846 on February 6, 2003. The Japanese Patent Applications name Honjo, Iwai, and Minato as the sole inventors. Ono filed the Japanese Patent Applications secretly, without informing either Freeman or Wood.

25. On July 2, 2003, without informing Freeman or Wood, Ono secretly filed PCT Application No. PCT/JP03/08420 (the “PCT Application”), a utility application that claims priority to the Japanese Patent Applications. The PCT Application names Honjo, Iwai, Minato, and Shibayama as sole inventors.

26. On September 29, 2009, the United States Patent and Trademark Office (USPTO) issued the ’048 patent. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the ’048 patent to name Freeman and Wood as co-inventors.

27. On May 1, 2012, the United States Patent Office issued the '179 patent. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the '179 patent to name Freeman and Wood as co-inventors.

28. On May 20, 2014, the United States Patent Office issued the '474 patent. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the '474 patent to name Freeman and Wood as co-inventors.

29. On June 30, 2015, the United States Patent Office issued the '999 patent. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the '999 patent to name Freeman and Wood as co-inventors.

30. On July 7, 2015, the United States Patent Office issued the '994 patent. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the '994 patent to name Freeman and Wood as co-inventors.

31. On August 2, 2016, the United States Patent Office issued the '899 patent. On June 12, 2019, this Court ordered the USPTO to issue a certificate of correction of the '899 patent to name Freeman and Wood as co-inventors.

32. Each of the Honjo-Freeman Patents expires in either 2023 or 2024.

Dana-Farber's Action to Correct Inventorship

33. On September 25, 2015, Dana-Farber filed an action in the District of Massachusetts for correction of inventorship of the Honjo-Freeman Patents. *See* Dkt. No. 1, Compl., *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Sept. 25, 2015).

34. As Dana-Farber stated in its Complaint, in requesting correction of inventorship it sought "to confirm its ability to grant non-exclusive licenses to companies interested in

developing cancer immunotherapies directed to the PD-1/PD-L1 pathway, in order to ensure broad patient access to the cancer treatments claimed in the Patents.” *Id.*, ¶ 56; Dkt. No. 98, Am. Compl., ¶ 64, *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Jan. 3, 2017).

35. Following a nine-day bench trial, the Court issued its findings of fact and conclusions of law on May 17, 2019. In that decision, the Court concluded that Dana-Farber presented clear and convincing evidence demonstrating that Freeman and Wood are joint inventors of the Honjo-Freeman Patents.

36. The Federal Circuit affirmed the Court’s judgment, holding that “the decision in this appeal rests on the extensive factual determinations made by the district court relating to the work performed together by Drs. Wood and Freeman, and Dr. Honjo that were not clearly erroneous, and the court made no errors of law.” *Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co.*, 964 F.3d 1365, 1374 (Fed. Cir. 2020).

37. Freeman’s experimental work contributing to the Honjo-Freeman Patents was performed in Boston, Massachusetts.

38. Freeman and Wood’s contributions were shared contemporaneously with Ono, both by written communications sent from Massachusetts and at in-person meetings in Massachusetts. Indeed, Ono participated in multiple collaboration meetings with Freeman and Wood from the outset of their collaboration. At least two of those meetings took place in Cambridge, Massachusetts. In those meetings, Freeman confidentially shared research data from his laboratory at Dana-Farber. Many of the documentary notes and meeting minutes confirming Freeman and Wood’s contributions come from Ono’s files and were in its possession since the 1999-2000 time period.

39. As Defendants acknowledged at the inventorship trial, much of the evidence of Freeman's contributions is undisputed. Despite Defendants' knowledge of Freeman and Wood's inventive contributions as reflected in hundreds of contemporaneous documents and later sworn deposition testimony, and even after being served with Dana-Farber's 2015 Complaint, they refused voluntarily to correct inventorship of the Honjo-Freeman Patents to make Freeman a joint inventor and Dana-Farber a co-owner.

40. Following this Court's decision, BMS stated, "It's important to note that today's decision does not impact our other intellectual property covering Opdivo." However, in its patent infringement lawsuits against Merck, Pfizer, Genentech, and AstraZeneca, BMS asserted only the '474 patent, the '999 patent, the '994 patent, and the '899 patent, each of which this Court ordered to be corrected to name Freeman and Wood as inventors.

41. The United States Patent and Trademark Office has issued Certificates of Correction for each of the Honjo-Freeman Patents that add Freeman and Wood as inventors.

Defendants Refuse to Correct Additional Patents in the Same Family

42. In 2016, after the Dana-Farber litigation commenced, Ono and Honjo filed two additional patent applications in the same family as the Honjo-Freeman Patents, which thereafter issued as the '301 patent and the '962 patent. Copies of the '301 patent and the '962 patent are attached hereto as Exhibits A and B, respectively.

43. On July 19, 2016, the United States Patent Office issued the '301 patent, titled "Immunopotentiative Composition." The '301 patent claims priority to the same Japanese patent applications as the Honjo-Freeman Patents (Japanese Patent Applications 2002-194491 and 2003-029846). It shares a common specification with the Honjo-Freeman Patents. The '301 patent is co-assigned to Ono and Tasuku Honjo. It names as inventors the same four Japanese inventors as

were named on the Honjo-Freeman Patents: Honjo, Nagahiro Minato, Yoshiko Iwai, and Shiro Shibayama. Neither Freeman nor Wood is named as an inventor.

44. Claim 1 of the '301 patent is representative: "A method of treating a tumor in a human in need thereof comprising administering to the human an effective amount of a human or humanized anti-PD-L1 monoclonal antibody that inhibits an interaction between PD-1 and PD-L1 in combination with an effective amount of an anti-CTLA-4 antibody."

45. On September 13, 2016, the United States Patent Office issued the '962 patent, titled "Immunopotentiative Composition." The '962 patent claims priority to the same Japanese patent applications as the Honjo-Freeman Patents (Japanese Patent Applications 2002-194491 and 2003-029846). It shares a common specification with the Honjo-Freeman Patents. The '962 patent is co-assigned to Ono and Tasuku Honjo. It names as inventors the same four Japanese inventors as were named on the Honjo-Freeman Patents: Honjo, Nagahiro Minato, Yoshiko Iwai, and Shiro Shibayama. Neither Freeman nor Wood is named as an inventor.

46. Claim 1 of the '962 patent is representative: "A method of treating a tumor in a human in need thereof comprising administering to the human an effective amount of an anti-PD-L1 monoclonal antibody that inhibits an interaction between PD-1 and PD-L1 in combination with an effective amount of a chemotherapeutic drug."

47. On February 11, 2016, in response to Dana-Farber's Request for Production No. 1 in the inventorship case, Defendants affirmed in writing their agreement to produce all documents in their possession related to patent applications claiming priority to Japanese Patent Application No. 2002-194491 or Japanese Patent Application No. 2003-029846. *See* Defendants Tasuku Honjo, E. R. Squibb & Sons L.L.C., and Bristol-Myers Squibb Co.'s Objections and Responses to Plaintiff's First Set of Requests for Production at 10 (Feb. 11, 2016); Defendant Ono

Pharmaceutical Co. Ltd.'s Objections and Responses to Plaintiff Dana-Farber Cancer Institute Inc.'s Requests For Production (Nos. 1-47) at 10 (June 5, 2017).

48. The '301 and '962 patents, and the applications that led to their issuance, fall within the category of documents Defendants agreed to produce. However, at no time in the course of the inventorship litigation did Defendants produce or even bring to Dana-Farber's attention either patent or the applications that led to their issuance.

49. In their research collaboration with Honjo, Freeman and Wood made significant contributions to conception of the inventions claimed in the '301 and '962 patents. Their contributions include, at least, the same contributions that the Court found to be significant contributions to the conception of the Honjo-Freeman Patents: "their discovery of PD-L1 and PD-L2, their discoveries of blocking antibodies, Dr. Wood's discovery of the inhibitory interaction between PD-1 and PD-L1, and Dr. Freeman's discovery of the expression of PD-L1 on tumor cells." Decision at 104. The collaboration involved the same collaborative research the Court described with respect to the Honjo-Freeman Patents: "Dr. Honjo collaborated extensively with both Dr. Freeman and Dr. Wood from at least October 1999 until at least September 2000 through numerous meetings, joint authorship of scientific journal articles, written collaboration agreements, and sharing of experimental results and ideas." *Id.* at 5.

50. On November 30, 2020, counsel for Dana-Farber requested that Defendants correct the '301 patent and the '962 patent to add Freeman and Wood as inventors. Defendants have refused to do so.

51. The Court's findings in the inventorship case have preclusive effect and require that the inventorship of the '301 patent and the '962 patent be corrected.

52. Freeman is a joint inventor of one or more claims recited in the '301 patent and the '962 patent.

53. Wood is a joint inventor of one or more claims recited in the '301 patent and the '962 patent.

54. Dana-Farber, as Freeman's assignee, is a co-owner of the '301 patent and the '962 patent.

55. Due to Defendants' refusal to correct inventorship of the '301 and '962 patents, the two patents do not have common ownership with the Honjo-Freeman Patents.

56. During prosecution, the claims of the '962 patent were rejected for non-statutory double patenting over two previously issued Honjo-Freeman Patents, the '048 and '179 patents. In an office action, the examiner stated that the claims of the '962 patent are not patentably distinct from the claims of the prior '048 and '179 patents "because they are directed to methods comprising administering anti-PD-L1 antibodies to cancer patients."

57. The applicants overcame the examiner's double patenting rejection by filing a terminal disclaimer. Under the terminal disclaimer, the '962 patent is enforceable "only for and during such period that it and the prior patent[s are] commonly owned." 37 CFR 1.321(c)(3); *see STC.UNM v. Intel Corp.*, 754 F.3d 940 942-944 (Fed. Cir. 2014).

58. Because Dana-Farber is a co-owner of the '048 and '179 patents, the three patents are not commonly owned, and the '962 patent therefore is invalid and unenforceable. Only by correcting its inventorship to add Drs. Freeman and Wood as inventors and making Dana-Farber a co-owner can the invalidity and unenforceability of the '962 patent be cured.

59. The applicants did not file a terminal disclaimer in the '301 prosecution, but the claims of that patent likewise are invalid for non-statutory double patenting in the absence of a

terminal disclaimer. Not only are its claims not patentably distinct over the claims of the '048 and '179 patent, they are virtually identical to claims that issued in the prior '899 patent. For example, claim 1 of the '301 patent and claim 52 of the '899 patent each is directed to treating a tumor by administering an effective amount of PD-L1 antibody that inhibits the interaction between PD-1 and PD-L1 in combination with an effective amount of CTLA-4 antibody. The invalidity of the '301 patent over the three earlier Honjo-Freeman Patents can be overcome by filing a terminal disclaimer, but only if all four patents are commonly owned.

60. Because Dana-Farber is a co-owner of the '048, '179, and '899 patents, the '301 patent is not commonly owned with them, and the filing of a terminal disclaimer is not permitted. Only by correcting inventorship of the '301 patent to add Drs. Freeman and Wood as inventors and making Dana-Farber a co-owner can the invalidity of the '301 patent be cured.

Defendants Assert the Honjo-Freeman Patents Against Merck

61. On September 4, 2014, the U.S. Food and Drug Administration (the "FDA") approved Merck & Co.'s ("Merck") PD-1 blocking antibody Keytruda® (pembrolizumab) for the treatment of "patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF Inhibitor."

62. That same day, Defendants and Honjo filed a patent infringement lawsuit in the District of Delaware against Merck, BMS's primary competitor in the area of PD-1-related cancer immunotherapy. Defendants did not seek Dana-Farber's consent to sue Merck for patent infringement, knowing that if they had recognized Dana-Farber as a co-owner of the asserted patent, they would not have had standing to sue Merck for patent infringement.

63. Under U.S. patent laws, all co-owners of a patent must join as plaintiffs to have standing to sue for patent infringement.

64. Defendants' lawsuit against Merck alleged that "[b]y virtue of obtaining approval to market and sell pembrolizumab [Keytruda®] as a treatment for certain patients with melanoma, Merck has the specific intent to cause infringement of the 474 patent or, at a minimum, Merck has been willfully blind to the infringement of the 474 patent that will inevitably result." Compl., ¶ 22, *Bristol-Myers Squibb Co. v. Merck & Co. Inc.*, No. 14-01131-GMS (D. Del. Sept. 4, 2014).

65. On December 22, 2014, the FDA approved BMS's PD-1 antibody Opdivo® (nivolumab) for the same indication as Keytruda®.

66. The FDA has since approved both Keytruda® and Opdivo® for additional cancer indications.

67. In 2015, Defendants filed two additional patent infringement lawsuits against Merck based on its alleged infringement of the '994 patent and the '999 patent through its manufacture and sale of Keytruda®. The cases were consolidated in the District of Delaware for discovery. Defendants again did not seek Dana-Farber's consent to sue Merck for patent infringement, knowing that if they had recognized Dana-Farber as a co-owner of the asserted patent, they would not have had standing to sue Merck for patent infringement.

68. Defendants were represented in the Merck case in Delaware by the same lead attorneys from the law firm of Akin Gump who also served as lead counsel for Defendants in Dana-Farber's correction of inventorship case in Massachusetts.

69. Defendants had standing to sue Merck only because, at the time, they and their co-defendant Honjo were the only parties with ownership rights in the Honjo-Freeman Patents. In other words, but for the omission of Freeman as a named inventor on the '474, '999, and '994 patents, Defendants could not have sued Merck for patent infringement without Dana-Farber's

participation and consent. Defendants thus obtained substantial competitive benefits by their omission of Freeman as an inventor of the Honjo-Freeman Patents, their refusal voluntarily to correct inventorship, and their efforts to obstruct, prolong and delay judicial correction of inventorship of the Honjo-Freeman Patents.

70. In suing Merck for patent infringement in Delaware, Defendants and Honjo falsely and unfairly held themselves out as the sole owners of the Honjo-Freeman Patents.

71. On January 1, 2017, more than a year after Dana-Farber sued for correction of inventorship but before this Court's order correcting inventorship, Defendants used their litigation leverage against Merck to negotiate a highly profitable settlement of the Merck litigation. Under the terms of the settlement, Merck obtained a license to the Honjo-Freeman Patents in exchange for an upfront payment of \$625 million plus an ongoing royalty of 6.5% on worldwide sales of Merck's PD-1 product Keytruda®.

72. A condition of Defendants' license agreement with Merck was Merck's covenant never to seek or obtain a license of any of the Honjo-Freeman Patents from any third party. By its terms, this prohibition survives even termination of Merck's license agreement with Defendants, and it permanently prevents Merck from negotiating a license agreement with Dana-Farber to obtain access to the Honjo-Freeman Patents, even if Dana-Farber offered a lower royalty rate than Defendants. Merck is an existing Dana-Farber licensee with respect to other PD-1/PD-L1-related patents, and it benefits from a royalty rate much lower than the 6.5% that Defendants required in exchange for their grant of a license to the Honjo-Freeman Patents.

73. On information and belief, Merck has reported cumulative revenue of approximately \$34.5 billion from its sales of Keytruda®.

74. On information and belief, since January 1, 2017 to the date of this amended complaint, Merck has paid BMS and Ono approximately \$2.1 billion in royalties in addition to Merck's upfront payment of \$625 million.

75. BMS and Ono have publicly disclosed that, in exchange for exclusive rights in the Honjo-Freeman Patents and Ono's cooperation in patent litigation asserting the Honjo-Freeman Patents against third parties, BMS agreed to pay Ono 25% of all sublicensing income derived from the Honjo-Freeman Patents. On information and belief, Ono has received in excess of \$530 million from BMS on account of BMS's sublicense of the Honjo-Freeman Patents to Merck.

76. In order to have standing to bring the three patent infringement actions against Merck, and to settle those actions on terms that have enriched Defendants to the extent of more than \$2.7 billion in licensing fees and royalties, Defendants falsely asserted and warranted that they controlled exclusive rights to the Honjo-Freeman Patents. The effect of their actions was to deprive Dana-Farber of the opportunity to negotiate a royalty-bearing license with Merck and/or to share in the proceeds of Defendants' settlement with Merck. Defendants' false assertion of sole ownership of the Honjo-Freeman Patents gave them the negotiating leverage of an exclusive owner of the Honjo-Freeman Patents and unfairly enabled BMS to avoid competing with Dana-Farber for licensees and to avoid the cost of paying Dana-Farber to obtain an exclusive license of Dana-Farber's co-ownership rights, as it had with Ono.

77. Defendants unfairly and unjustly exploited and profited from their refusal to correct inventorship of the Honjo-Freeman Patents in 2015 or thereafter and their refusal to recognize Dana-Farber's co-ownership rights in the Honjo-Freeman Patents.

Defendants Assert a Honjo-Freeman Patent against Additional Parties

78. In 2016, the FDA approved Tecentriq®, an anti-PD-L1 antibody developed by Genentech, for the treatment of urothelial carcinoma. In 2017, the FDA approved Bavencio®, an anti-PD-L1 antibody developed by Pfizer and EMD Serono, Inc., for the treatment of metastatic Merkel cell carcinoma. In 2017, the FDA approved Imfinzi®, an anti-PD-L1 antibody developed by AstraZeneca, for the treatment of bladder cancer and some types of lung cancer.

79. In 2017, while Dana-Farber's action to correct inventorship was pending in Massachusetts federal court, Defendants and Honjo filed additional patent infringement actions in the District of Delaware against Genentech, Pfizer, and AstraZeneca asserting infringement of the '899 patent. As the Defendants and Honjo stated in their complaint against Genentech, "[t]he claims of the '899 patent are generally directed to methods of treating cancer by administering an anti-PD-L1 monoclonal antibody that inhibits the interaction between PD-1 and PD-L1." Compl., ¶ 22, *Bristol-Myers Squibb Co. v. Genentech, Inc.*, No. 17-01027-GMS (D. Del. July 26, 2017).

80. Had Freeman been named as an inventor on the '899 patent, Dana-Farber would have been a co-owner of the '899 patent, and Defendants would not have had standing to sue Genentech, Pfizer, and AstraZeneca for infringement of the '899 patent without Dana-Farber's consent and participation.

81. On February 4, 2019, on the eve of trial in Massachusetts on Dana-Farber's complaint for correction of inventorship, Defendants entered into a settlement agreement with Pfizer, announced in court in Boston on February 5, 2019. As in the Merck license, Defendants required Pfizer to agree, as a condition of the license, that it would never seek or obtain a license

from any third party (i.e., Dana-Farber), even if Pfizer's license from Defendants were later terminated. In contrast to the Merck license, in which Defendants required Merck to pay \$625 million upfront plus ongoing royalties in exchange for a license to the Honjo-Freeman Patents, in the Pfizer agreement Defendants granted Pfizer a license to the Honjo-Freeman Patents without requiring *any* payment by Pfizer. On the contrary, under the terms of the license, Defendants ***agreed to pay Pfizer*** an upfront fee. In addition, BMS and Ono agreed to pay Pfizer an ongoing share of BMS's royalties from sublicensing. BMS and Ono agreed to these financial benefits to Pfizer to induce Pfizer to withdraw its claim that Freeman and Wood were co-inventors of the Honjo-Freeman Patents and to take steps dictated by Defendants to obstruct and impede Dana-Farber's prosecution of its inventorship claims.

82. Defendants' license agreement with Merck included covenants that Merck would not challenge the inventorship of the Honjo-Freeman Patents or support a third party inventorship challenge, and would not provide any attorney work product concerning incorrect inventorship to any third party. At the time Merck agreed to these covenants, Dana-Farber's inventorship litigation had been pending for over a year and Merck had conducted discovery on closely related issues in the Delaware infringement case. Defendants' insistence that Merck not cooperate with Dana-Farber in prosecuting its inventorship claims obstructed Dana-Farber's prosecution of its inventorship case and imposed added costs on the litigation.

83. Defendants' license agreement with Pfizer included covenants expressly directed to the inventorship trial that was to begin the next day. In exchange for the upfront payment and share of future royalties provided to Pfizer by Defendants, Pfizer agreed not to "[s]upport DFCI in any pending Legal Proceedings among DFCI and the BMS/Ono Parties" and further promised that "no Pfizer consultants or advisors shall participate as witnesses (unless by operation of a

valid subpoena) or consultants or advisors in connection with any such Legal Proceeding.” As a consequence, Pfizer’s corroborating witnesses, who were scheduled to testify on the first day of trial, suddenly became unavailable, including one witness who abruptly boarded a flight out of Boston that morning and was no longer subject to the Court’s subpoena power. Defendants also agreed to pay Pfizer a monetary *bonus* in the event Defendants prevailed in defeating Dana-Farber’s inventorship claim and preventing Dana-Farber from becoming a co-owner of the Honjo-Freeman Patents.

84. Defendants’ conduct with respect to their settlements with Merck and Pfizer was calculated to harm Dana-Farber in Massachusetts, to obstruct correction of inventorship of the Honjo-Freeman Patents to make Dana-Farber a co-owner, and to interfere with Dana-Farber’s ability to exercise its rights as a co-owner by entering into license agreements with third parties.

85. The licenses to the Honjo-Freeman Patents granted by Defendants imposed restrictive and anticompetitive covenants that prevented the licensees from ever seeking or obtaining a license to the Honjo-Freeman Patents from Dana-Farber even if such a license were available at lower cost. These covenants preemptively prevented Dana-Farber from competing with Defendants for hundreds of millions or billions of dollars of licensing business from third party manufacturers of PD-1/PD-L1 therapies and had the effect of increasing the manufacturers’ cost of providing PD-1/PD-L1 therapies to cancer patients.

Defendants Grant an Additional License of the Honjo-Freeman Patents by Falsely Claiming to Be Exclusive Owners

86. Regeneron Pharmaceuticals, Inc. (“Regeneron”) is a biopharmaceutical company located in Tarrytown, New York.

87. Sanofi-aventis U.S. LLC is a U.S. subsidiary of the French multinational pharmaceutical company Sanofi. Sanofi-aventis U.S. LLC is headquartered in Bridgewater, NJ 08807.

88. On September 28, 2018, the FDA approved Regeneron and sanofi-aventis U.S. LLC's co-marketed product Libatyo®, an anti-PD-1 antibody, for the treatment of metastatic cutaneous squamous cell carcinoma ("CSCC") or locally advanced CSCC for patients who are not candidates for curative surgery or curative radiation. Libatyo® was the third anti-PD-1 antibody approved by the FDA.

89. In August 2018, nearly three years after Dana-Farber sued Defendants to correct inventorship, Defendants negotiated a license agreement with Regeneron and Sanofi. Defendants have publicly stated that under this agreement, Regeneron and Sanofi obtained non-exclusive rights in the Honjo-Freeman Patents in exchange for an up-front payment of \$20 million and royalties of 8.0% on worldwide sales of their PD-1 product through December 31, 2023.

90. On information and belief, Defendants used the threat of patent infringement litigation against Regeneron and Sanofi as leverage to negotiate the license agreement. But for Defendants' refusal to provide Dana-Farber co-ownership rights in the Honjo-Freeman Patents, Defendants would have not have standing to sue Regeneron and Sanofi for infringement of the Honjo-Freeman Patents and would not have been able to use the threat of patent litigation to negotiate a license agreement with Regeneron and Sanofi on favorable terms.

91. On information and belief, in entering into their license agreement with Regeneron and Sanofi in 2018, Defendants falsely asserted and warranted that they controlled exclusive rights to the Honjo-Freeman Patents and thus unfairly and unjustly profited from

Defendants' refusal to recognize Dana-Farber's co-ownership rights in the Honjo-Freeman Patents.

92. On information and belief, to date Defendants have received approximately \$194 million in licensing fees and royalties from Sanofi and Regeneron.

93. On information and belief, Defendants' license agreement with Sanofi and Regeneron contains restrictive covenants similar to those contained in the Merck and Pfizer licenses for the purpose of obstructing, hindering, and impeding Dana-Farber's efforts to license the Honjo-Freeman Patents.

94. In an Order dated December 6, 2017, the Court in the inventorship case ordered Defendants to produce all agreements and other documents reflecting their receipt of "royalties, licensing fees or other compensation" relating to the Honjo-Freeman Patents. Dkt. 185; *see* Dkt. 162, para. 3. The Regeneron/Sanofi license agreement entered into by Defendants in August 2018 falls within the scope of the Court's discovery order. However, at no time after their execution of the agreement did Defendants produce it, and to date they have not provided Dana-Farber with a copy of it.

Defendants' Unfair Methods of Competition, Unfair Trade Practices, and Interference in Dana-Farber's Licensing Negotiations After Correction of the Honjo-Freeman Patents

95. Defendants' pattern of obstruction, unfair competition, unfair trade practices, and interference with Dana-Farber's exercise of its co-ownership rights continued unabated even after the Court ordered correction of inventorship of the Honjo-Freeman Patents.

96. On May 29, 2019, shortly after the Court's May 17, 2019 Decision ordering correction of inventorship, representatives from a Massachusetts-based biopharmaceutical company (Company A), approached Dana-Farber to propose that Dana-Farber grant it a non-exclusive license to the Honjo-Freeman Patents. Company A has an ongoing business

relationship with Dana-Farber with respect to other patents related to the subject matter of the Honjo-Freeman Patents.

97. Two days later, on Friday, May 31, 2019, Company A emailed Dana-Farber an outline of the principal terms of its proposed license, including specific royalty terms.

98. On June 10, 2019, Company A abruptly informed Dana-Farber that it no longer wished to pursue a license from Dana-Farber.

99. On information and belief, Company A's withdrawal of its offer resulted from communications to it from representatives of BMS.

100. On information and belief, Defendants knowingly interfered with Dana-Farber's prospective licensing opportunity and induced Company A not to enter into a licensing agreement with Dana-Farber.

101. In the fall of 2020, Dana-Farber was engaged in negotiations with another prospective licensee of the Honjo-Freeman Patents ("Company B"). Dana-Farber believed that the parties had reached alignment on a term sheet covering the principal financial terms for the license. In the midst of these discussions, Company B abruptly informed Dana-Farber that it had instead entered into a license agreement with Defendants. On information and belief, Defendants knowingly interfered with Dana-Farber's prospective licensing opportunity and induced Company B not to enter into a licensing agreement with Dana-Farber by using its market power in the field of PD-1/PD-L1 intellectual property to pressure Company B not to deal with Dana-Farber.

102. On information and belief, Defendants have asserted to prospective licensees of the Honjo-Freeman Patents that their products not only infringe the Honjo-Freeman Patents but also infringe additional patents held by Defendants, including a separate patent family that

claims antibody sequences capable of blocking the PD-1/PD-L1 pathway (the “Korman Patents”). On information and belief, Defendants have unfairly used their market power in the Korman Patents and/or other patents to license the Honjo-Freeman Patents by either (a) conditioning licenses to the Korman Patents or other patents on taking a license to the Honjo-Freeman Patents from Defendants rather than from Dana-Farber, or (b) demanding higher royalties on the Korman Patents or other patents when licensed alone than if licensed together with the Honjo-Freeman Patents.

103. On information and belief, in negotiations with prospective licensees of the Honjo-Freeman Patents, Defendants also have demanded that licensees agree not accept a license to the Honjo-Freeman Patents from Dana-Farber even if Defendants later terminate their license and even if Dana-Farber offers more favorable financial terms.

Defendants’ Pattern of Obstruction and Delay

104. Between September 2015 and May 2019, Defendants refused voluntarily to correct inventorship of the Honjo-Freeman Patents despite knowing of Freeman’s contributions to conception of the claimed inventions, and took steps intentionally, maliciously and in bad faith, to obstruct, hinder, and delay correction of inventorship. On information and belief, the purpose of Defendants’ tactics, before, during, and after Dana-Farber sued for correction of inventorship, was to allow Defendants to maintain standing to assert the Honjo-Freeman Patents against potential third party licensees, to prevent Dana-Farber from licensing the Honjo-Freeman Patents non-exclusively to potential licensees, and to interfere with Dana-Farber’s ability to realize licensing revenue as a co-owner of the Honjo-Freeman Patents.

Defendants' Unfair Methods of Competition, Unfair Trade Practices, and Tortious Interference with Dana-Farber's Business Relationships Have Deprived Dana-Farber of Licensing Revenue

105. Defendants' unfair methods of competition, unfair trade practices, and tortious interference in Dana-Farber's licensing negotiations have prevented Dana-Farber from licensing the Honjo-Freeman Patents and enjoying the financial rewards of co-ownership. Defendants have derived substantial economic benefit from their misconduct and their refusal to correct inventorship of the Honjo-Freeman Patents to recognize Dana-Farber's rights as a co-owner.

106. To date, numerous biotechnology companies have developed or are developing antibodies against PD-1 and PD-L1 for treatment of cancer, including Merck, Regeneron, Novartis, Tesaro (a GSK company), Roche-Genentech, Pfizer, and AstraZeneca. Other companies are investigating additional PD-1 and PD-L1 therapies covered by one or more of the Honjo-Freeman Patents.

107. Dana-Farber has previously licensed to third parties other patents it owns or co-owns relating to modulation of the PD-1/PD-L1 pathway to treat disease. Among the many companies it has licensed are BMS, Merck, Genentech, Novartis, AstraZeneca, Boehringer Ingelheim, Amplimmune, and EMD Serono. Dana-Farber's objective is and always has been ensuring broad patient access to the cancer treatments claimed in the Honjo-Freeman Patents. Dana-Farber licenses its innovative research broadly to help support its mission as a worldwide leader in cancer research and to help encourage the translation of its scientific discoveries into drug development. Dana-Farber thus is in the business of non-exclusively licensing technology related to the PD-1/PD-L1 pathway.

108. Upon information and belief, Defendants were aware of these past licensing relationships and, indeed, BMS and its subsidiary Medarex were among Dana-Farber's licensees. Defendants were also aware at least since 2015 of Dana-Farber's intent "to grant non-exclusive

licenses to companies interested in developing cancer immunotherapies directed to the PD-1/PD-L1 pathway, in order to ensure broad patient access to the cancer treatments claimed in the Patents.” Dkt. No. 1, Compl., ¶ 56 *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Sept. 25, 2015); Dkt. No. 98, Am. Compl., ¶ 64, *Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd. et al.*, No. 15-13443-PBS (D. Mass. Jan. 3, 2017).

109. Dana-Farber’s technology transfer mission is well known among pharmaceutical companies. Indeed, Dana-Farber describes many of its technologies available for licensing on its website.

110. But for Defendants’ actions in refusing voluntarily to provide Dana-Farber co-ownership rights in the Honjo-Freeman Patents after knowing the grounds for Dana-Farber’s claim, and but for Defendants’ unfair methods of competition and unfair trade practices before, during and after Dana-Farber’s suit for correction of inventorship, Dana-Farber would have granted royalty-bearing licenses to multiple companies developing and/or marketing PD-1 or PD-L1 antibodies for treatment of cancer, including, without limitation, one or more of the companies identified in paragraph 106, above.

111. As an example of the value Dana-Farber derives from its PD-/PD-L1 related licensing efforts, in August 2016, Dana-Farber entered into an agreement with CPPIB Credit Europe S.à r.l., a wholly owned subsidiary of Canada Pension Plan Investment Board to monetize a portion of its interest in royalties defined by certain licensing agreements related to its PD-L1 intellectual property. CPPIB has paid Dana-Farber \$168 million pursuant to this monetization agreement.

112. Defendants' actions seeking to hinder, obstruct, and delay Dana-Farber from securing and exercising its co-ownership rights to the Honjo-Freeman Patents, the '301 patent, and the '962 patent, while simultaneously licensing the Honjo-Freeman Patents to Dana-Farber's business partners and prospective licensees, have interfered with Dana-Farber's business relationships and had the effect of preventing Dana-Farber from entering into licensing agreements with its prospective business partners and receiving licensing revenues. On information and belief, Defendants continue to prevent Dana-Farber from fairly competing by coercing licensees into agreeing not to take a license from Dana-Farber, and Defendants are employing unfair methods of competition and unfair trade practices, including using their other patents as leverage to pressure licensees to license the Honjo-Freeman Patents from Defendants rather than from Dana-Farber.

113. As of the date of this Amended and Supplemental Complaint, Dana-Farber has received none of the substantial economic benefits realized by Defendants through their exploitation of Freeman's patented work and refusal to recognize Dana-Farber's co-ownership rights in the Honjo-Freeman Patents.

114. Dana-Farber has suffered substantial damages by reason of Defendants' conduct described herein. In addition, Defendants have been unjustly enriched by the settlement proceeds, licensing fees, royalties, and/or other payments they have received from third parties in connection with the Honjo-Freeman Patents as described herein.

Count I
(Unfair Methods of Competition and Unfair Trade Practices)

115. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 114 of the Amended and Supplemental as if those allegations have been set forth herein.

116. Dana-Farber, BMS, and Ono, as owners, licensees, and/or licensors of intellectual property are and have been engaged in trade or commerce within the meaning of Mass. G.L. ch. 93A, §§ 2 and 11 at all times relevant to this Complaint.

117. Defendants have employed unfair methods of competition and have committed unfair trade practices within the meaning of Mass. G. L. ch. 93A, §§ 2 and 11 by depriving Dana-Farber of its lawful rights as a co-owner of the Honjo-Freeman Patents, by unfairly competing with Dana-Farber in licensing the Honjo-Freeman Patents, and by interfering with Dana-Farber's business relationships with potential licensees, including potential licensees operating in Massachusetts.

118. Defendants held themselves out as the exclusive owners of the Honjo-Freeman Patents while knowing of Freeman's contributions to the Honjo-Freeman Patents and asserted or threatened to assert the Honjo-Freeman Patents against multiple competitors. Defendants have unfairly seized all the economic benefits and value from the Honjo-Freeman Patents, extracting more than \$3 billion in licensing revenues to date while Dana-Farber has received nothing.

119. Defendants attempted to prolong their ability falsely to assert that they were exclusive owners of the Honjo-Freeman Patents through bad faith, obstructionist litigation tactics and by imposing restrictive covenants directed to Dana-Farber in their license agreements.

120. By way of example, in February 2016, Ono moved to dismiss Dana-Farber's inventorship complaint for lack of personal jurisdiction. This motion was frivolous and filed in bad faith. Ono's motion did not disclose to the Court its contacts with Massachusetts during the research collaboration that led to the Honjo-Freeman Patents, including the participation of Ono scientist and named inventor Shibayama in collaboration meetings in 1999 and 2000 in Cambridge, Massachusetts. Defendants used the pendency of Ono's jurisdictional motion to

justify obtaining and extending a stay of the case that lasted until 2017, after Defendants had successfully negotiated their \$625 million settlement with Merck. In April 2017, just before a scheduled hearing on Ono's motion, Ono suddenly withdrew the motion, offering no plausible explanation and implicitly admitting that Ono's motion was not filed in good faith.

121. By way of further example, Defendants' license with Merck prevented Merck from ever licensing the Honjo-Freeman Patents from Dana-Farber at a lower cost, and their licenses with both Merck and Pfizer prevented each of them from cooperating with Dana-Farber as Dana-Farber prosecuted its inventorship claims. Defendants' license agreement with Pfizer, struck the day before the inventorship trial began, named Dana-Farber directly and even promised to pay Pfizer a bonus if Defendants defeated Dana-Farber's inventorship claims. As a result of the obstructionist and anticompetitive covenants Defendants imposed on Pfizer, witnesses scheduled to testify on the first day of trial were suddenly and unexpectedly unavailable.

122. On information and belief, Defendants continue to demand that prospective licensees not take a license to the Honjo-Freeman Patents from Dana-Farber even if the license agreement is terminated and Dana-Farber offers to license at lower cost.

123. On information and belief, Defendants have unfairly used leverage from the Korman Patents and/or other patents in negotiating with prospective licensees of the Honjo-Freeman Patents. On information and belief, Defendants have unfairly used their market power in the Korman Patents and/or other patents to license the Honjo-Freeman Patents either by (a) conditioning licenses to the Korman Patents or other patents on taking a license to the Honjo-Freeman Patents from Defendants rather than from Dana-Farber, or (b) demanding higher

royalties on the Korman Patents or other patents when licensed alone than if licensed together with the Honjo-Freeman Patents.

124. On information and belief, Defendants interfered with Dana-Farber's business relationships by employing unfair methods of competition and unfair trade practices to induce at least Merck, Regeneron/Sanofi, Company A, and Company B not to enter into business relationships with Dana-Farber to license technology directed to the use of the antibodies to block the PD-L1/PD-1 pathway for treatment of cancer, as claimed in the Honjo-Freeman Patents.

125. Defendants' employment of the unfair methods of competition and the unfair trade practices described above knowingly and/or willfully violated Mass. G. L. ch. 93A, §§ 2 and 11.

126. Dana-Farber suffered substantial injury by reason of Defendants' employment of unfair methods of competition and unfair trade practices.

127. Defendants' unfair methods competition and unfair trade practices occurred primarily and substantially within Massachusetts.

Count II
(Tortious Interference with Prospective Business Relations)

128. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 127 of the Amended and Supplemental Complaint as if those allegations have been set forth herein.

129. Dana-Farber has had present and/or prospective business relationships for licensing intellectual property related to the PD-1/PD-L1 pathway with companies developing and marketing cancer immunotherapy drugs related to the PD-1/PD-L1 pathway. Those business

relationships include, but are not limited to, relationships with Merck, Genentech, AstraZeneca, and EMD Serono.

130. On information and belief, BMS and Ono knowingly induced at least Merck, Regeneron/Sanofi, Company A, and Company B not to enter into business relationships with Dana-Farber to license technology directed to the use of the antibodies to block the PD-L1/PD-1 pathway for treatment of cancer, as claimed in the Honjo-Freeman Patents.

131. In inducing these companies not to enter into business relationships with Dana-Farber, Defendants possessed an improper motive or means. Defendants falsely held themselves out to prospective licensees as the sole owners of the Honjo-Freeman Patents and were able to do so only by hindering, delaying, and obstructing correction of inventorship of the Honjo-Freeman Patents. Defendants have used their license agreements to further obstruct correction of inventorship. The licenses with at least Merck and Pfizer contained restrictive covenants directed to Dana-Farber that interfered with Dana-Farber's prosecution of its correction of inventorship claims, including Defendants' agreement to pay Pfizer to take a license in exchange for Pfizer's cooperation in obstructing Dana-Farber's inventorship case. Defendants have baselessly and in bad faith refused to correct inventorship to add Freeman and Wood as joint inventors on two additional patents, the '301 patent and the '962 patent, where correction of inventorship is required as a matter of law by the Court's Decision. In addition, on information and belief, Defendants have used their ownership of these and other patents, and are continuing to use their ownership of these and other patents, to pressure licensees to license from Defendants rather than from Dana-Farber, even if doing so requires the licensee to pay more in royalties and increase its costs of goods unnecessarily.

132. Dana-Farber suffered substantial economic harm by its loss of the foregoing business opportunities.

Count III
(Unjust Enrichment - Contract)

133. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 132 of the Amended and Supplemental Complaint as if those allegations have been set forth herein.

134. Dana-Farber conferred benefits upon Defendants, including at least the information, data, discoveries and/or materials that Freeman confidentially and in good faith shared with Honjo during their collaboration between 1999 and 2002 pursuant to oral and written agreements. Defendants were aware of the benefit of these many contributions.

135. Ono and, later, BMS, accepted the benefits conferred upon them by Dana-Farber. Defendants have wrongfully exploited the benefit of Dana-Farber and Freeman's confidential discoveries, ideas, and materials by falsely holding themselves out as the exclusive owners of the Honjo-Freeman Patents, enabling them to assert, or threaten to assert, the Honjo-Freeman Patents against their competitors and to license the Honjo-Freeman Patents to third parties in exchange for more than \$3 billion in licensing revenues. To further their ability wrongfully to hold themselves out as exclusive owners of the Honjo-Freeman Patents, Defendants' licenses with at least Merck and Pfizer contained restrictive and anticompetitive covenants directed to Dana-Farber that were intended to interfere with Dana-Farber's prosecution of its correction of inventorship claims. To date, Defendants have not shared any of the benefits of their licenses or their false claims of exclusivity with Dana-Farber.

136. The retention of these benefits by Defendants has been and continues to be unjust, unfair, and inequitable. By reason of Defendants' conduct, Dana-Farber was wrongfully

prevented from realizing its federally-protected rights and benefits as a co-owner of the Honjo-Freeman Patents and forced to forego valuable licensing opportunities.

137. Defendants have derived, and will continue to derive, substantial revenue from their licensing of the Honjo-Freeman Patents to Merck, Regeneron-Sanofi, and Company B without compensating Dana-Farber, either for the value of exclusive patent rights effectively misappropriated by Defendants or for the value of Dana-Farber's lost licensing opportunities. Defendants have deprived Dana-Farber of the economic advantages and benefits it would have enjoyed had it not been for Defendants' unfair, inequitable, and wrongful conduct.

138. Defendants have been unjustly enriched at Dana-Farber's expense by their continued exploitation and profit from the Honjo-Freeman Patents, and by their continuing refusal to recognize Dana-Farber's rights as a co-owner of the Honjo-Freeman Patents and the '301 and '962 patents.

Count IV
(Constructive Trust)

139. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 138 of the Amended and Supplemental Complaint as if those allegations have been set forth herein.

140. Defendants have derived substantial financial benefits from their patent infringement action against Merck and their subsequent settlement and license agreement with Merck in 2017. Defendants did not join Dana-Farber as a co-owner of the asserted patents in that action or seek Dana-Farber's consent to bring suit against Merck.

141. Defendants have been unjustly enriched at Dana-Farber's expense by their continued exploitation of and profit from the Honjo-Freeman Patents, all derived from the

research and materials that Dana-Farber and Freeman shared with them, and by their refusal timely to recognize Dana-Farber's rights as a co-owner of the Honjo-Freeman Patents.

142. As an equitable remedy, the Court should impose a constructive trust for the benefit of Dana-Farber providing for Dana-Farber's receipt of an equitable share of the proceeds realized from Defendants' agreements with Merck, Regeneron/ Sanofi, Company B, and any other license agreement with any other prospective licensee or company that develops a PD-1 or PD-L1 therapy for treatment of cancer.

Count V
(Correction of Inventorship of United States Patent No. 9,393,301)

143. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 142 of the Amended and Supplemental Complaint as if those allegations have been set forth herein.

144. Freeman and Wood each made significant contributions to the conception of the subject matter claimed in the '301 patent.

145. The Court's findings as to Freeman's and Wood's contributions to the Honjo-Freeman Patents apply equally to the '301 patent and have preclusive effect.

146. Freeman and Wood are joint inventors of the '301 patent.

Count VI
(Correction of Inventorship of United States Patent No. 9,439,962)

147. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 146 of the Amended and Supplemental Complaint as if those allegations have been set forth herein.

148. Freeman and Wood each made significant contributions to the conception of the subject matter claimed in the '962 patent.

149. The Court's findings as to Freeman's and Wood's contributions to the Honjo-Freeman Patents apply equally to the '962 patent and have preclusive effect.

150. Freeman and Wood are joint inventors of the '962 patent.

Count VII

(In the Alternative, Invalidity and Unenforceability of United States Patent Nos. 9,393,301 and 9,439,962)

151. Dana-Farber repeats and realleges the allegations set forth in paragraphs 1 through 150 of the Amended and Supplemental Complaint as if those allegations have been set forth herein.

152. Unless inventorship of the '301 and '962 patents is corrected to add Freeman and Wood as inventors, the '301 and '962 patents are invalid for incorrect inventorship.

153. The USPTO rejected all claims of the '962 patent for non-statutory double patenting over the claims of the '048 and '179 patents. The applicants, Ono and Honjo, overcome that rejection only by the filing of a terminal disclaimer.

154. Because the '962, '048, and '179 patents are not commonly owned, the '962 patent is unenforceable according to the terms of its terminal disclaimer and also is invalid for non-statutory double patenting.

155. The claims of the '301 patent are invalid for non-statutory double patenting over the claims of the '048, '179, and '899 patents. The invalidity of the '301 patent could be cured by the filing of a terminal disclaimer, but such a terminal disclaimer can be filed only if the '301 patent is commonly owned with the '048, '179, and '899 patents. Unless and until the '301 patent is corrected to name Freeman as an inventor and to make Dana-Farber a co-owner, the applicants cannot file a terminal disclaimer and the claims of the '301 patent are invalid.

156. As long as the '301 and '962 patents remain in existence and Dana-Farber is not made a co-owner thereof, Dana-Farber will be unfairly impeded in licensing the Honjo-Freeman Patents to third party manufacturers of PD-1/PD-L1 therapies, because potential licensees needing access to the entire patent family, including the '962 and '301 patents, will be unable to obtain freedom to operate by licensing from Dana-Farber rather than from Defendants.

157. Unless the '962 and '301 patents are corrected to add Freeman as an inventor and make Dana-Farber a co-owner, Dana-Farber is entitled to a declaration that the '301 patents and '962 patents are invalid and unenforceable.

PRAYERS FOR RELIEF

WHEREFORE, Dana-Farber Cancer Institute, Inc. respectfully requests that this Court:

- a. Enter judgment for Dana-Farber and against Defendants on Counts I-VII of this Complaint;
- b. Determine and declare that Freeman and Wood are joint inventors of the '301 patent and the '962 patent;
- c. Order the United States Patent and Trademark Office to correct inventorship of the '301 patent and the '962 patent by adding Freeman and Wood as joint inventors;
- d. In the alternative, if the Court does not grant the relief sought in prayers (b) and (c) and Ono does not correct inventorship voluntarily, determine and declare that the '301 and '962 patents are invalid and unenforceable;
- e. Award Dana-Farber monetary damages in an amount to be proven at trial for the economic injury it has sustained as a consequence of Defendants' actions;
- f. Award monetary damages against each of BMS and Ono in the amount of (1) the value of the benefits they received (in settlement proceeds, licensing fees, royalties or other monetary benefits) as a result of their employment of unfair methods of competition, unfair trade practices, and/or tortious interference with Dana-Farber's prospective business relationships, or (2) the value of the licensing opportunities Dana-Farber lost because of Defendants' employment of unfair

methods of competition, unfair trade practices, and/or tortious interference with Dana-Farber's prospective business relationships;

- g. Impose a constructive trust upon each of BMS and Ono for the benefit of Dana-Farber in the amount of (1) the value of the benefits they received (in settlement proceeds, licensing fees, royalties or other benefits) as a result of their employment of unfair methods of competition, unfair trade practices, and/or tortious interference with Dana-Farber's prospective business relationships, or (2) the value of the licensing opportunities Dana-Farber lost because of Defendants' employment of unfair methods of competition, unfair trade practices, and/or tortious interference with Dana-Farber's prospective business relationships, and upon imposing such trust, order BMS and Ono to transfer such fees or proceeds as BMS and Ono currently have in their possession;
- h. Award Dana-Farber treble the amount of any award of proceeds, profits or damages;
- i. Award Dana-Farber its reasonable attorneys' fees and costs pursuant to Mass. G.L. Ch. 93A, § 11, 35 U.S.C. § 285, and/or in the exercise of the Court's equitable discretion;
- j. Grant Dana-Farber such other and further relief that this Court deems just and proper.

Respectfully submitted,

DANA-FARBER CANCER INSTITUTE, INC.
By its attorneys,

/s/ Donald R. Ware

Donald R. Ware (BBO No. 516260)
Martin F. Murphy (BBO No. 363250)
Barbara A. Fiacco (BBO No. 633618)
Sarah S. Burg (BBO No. 683245)
Michael Hoven (BBO No. 688593)
Foley Hoag LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210-2600
(617) 832-1000 (telephone)
(617) 832-7000 (facsimile)

Dated: January 6, 2021

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document, filed under seal, will be served on counsel for Defendants by electronic mail on January 6, 2021.

/s/ Donald R. Ware

Donald R. Ware

Dated: January 6, 2021